

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 16-1024V
(to be published)

***** Chief Special Master Corcoran
M.R., *
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Petitioner, * Dated: October 3, 2022
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* v. *
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Ronald Craig Homer, Conway Homer, P.C., Boston, MA, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION¹

On August 18, 2016, M.R. filed a petition for compensation under the National Vaccine Injury Compensation Program (the “Program”).² ECF No. 1. Petitioner alleges that an influenza (“flu”) vaccination administered to him on October 21, 2014, caused him to experience left-sided sensorineural hearing loss (“SNHL”). An entitlement hearing in the matter was held on February 25, 2022, in Washington, D.C.

Having reviewed the record, all expert reports and associated literature, and listened to the witnesses who testified at the hearing, I hereby deny an entitlement award. As discussed in greater

¹ This Decision will be posted on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Ruling’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter “Vaccine Act” or “the Act”]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

detail below, Petitioner's acoustic neuroma/vestibular schwannoma was the most likely cause of his SNHL—not the flu vaccine.

I. Fact History

Vaccination and Onset of Symptoms

Petitioner was a forty-nine-year-old registered nurse when he received a flu vaccine in his left arm on October 21, 2014, at his place of employment, Robert Wood Johnson ("RWJ") University Hospital. Pet. 1 at 1; Ex. 18 at 1 ("M.R. Affidavit"). His past medical history was significant for morbid obesity, urinary tract stone disease, allergic rhinitis, elevated cholesterol/triglycerides, and elevated hemoglobin A1C in 2013. Ex. 2 at 2–5, 8–10, 23–24; Ex. 3 at 3–4. Petitioner had also previously received flu vaccines at work for at least the prior three years, but with no reported adverse events. Ex. 12 at 15.³

On October 27, 2014 (six days after vaccination), M.R. presented to the emergency room ("ER") of RWJ Hospital, "complaining of severe vertigo with hearing loss to the left ear." Ex. 7 at 113. Petitioner reported an "abrupt onset of painless vertigo beginning 2 days ago [on October 25th] that ha[d] been intermittent until today." *Id.* An ER physician treated Petitioner with Meclizine, which provided a "good relief of symptoms." *Id.* at 114. A CT scan revealed no abnormalities, and the examination yielded results deemed within normal limits except for some horizontal nystagmus.⁴ *Id.* at 115. Petitioner was diagnosed with acute labyrinthitis and discharged the same day. *Id.* at 113–14. The differential diagnoses included a cerebellopontine angle ("CPA") tumor. Tr. at 114–15

Petitioner next presented to otolaryngologist Dr. Michael Goldrich on October 30, 2014, complaining of "symptoms of vertigo since Saturday [October 25]." Ex. 5 at 43. Petitioner reported hearing loss in his left ear and one episode of nausea and vomiting. *Id.* An audiogram from that same day revealed profound sensorineural hearing loss in petitioner's left ear. *Id.* at 46, 54–55. Dr. Goldrich's impression was acute hearing loss and vertigo. *Id.* at 46.

The following day, Dr. Goldrich performed a left myringotomy, tube insertion, and steroid instillation. Ex. 7 at 1, 15, 50. Dr. Goldrich noted that "5 days [after] flu vaccine on 10/21/14 [patient with] reports of hearing loss [in his left] ear." *Id.* at 25. Both the preoperative and

³ Petitioner had volunteered for a non-contrast brain magnetic resonance imaging ("MRI") in February 2003, which was unremarkable except for mild sinus mucosal thickening. Ex. 20 at 1.

⁴ Nystagmus is defined as "an involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotatory, or mixed." *Nystagmus*, Dorland's Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=34565&searchterm=nystagmus> (last visited Oct. 3, 2022).

postoperative diagnoses were eustachian tube dysfunction and acute SNHL in Petitioner's left ear. *Id.* at 50.

On November 3, 2014,⁵ Petitioner saw Dr. Goldrich, whose continued assessment was that Petitioner had experienced acute hearing loss and vertigo. Ex. 5 at 40, 42. That same day, Petitioner had a hearing consultation with otolaryngology surgeon Jed Kwartler, M.D. Ex. 9 at 16. Petitioner indicated to Dr. Kwartler that his sudden hearing loss occurred about a week before. *Id.* He denied any recent viral illness, but mentioned that he had received the flu vaccine prior to the onset of his symptoms. *Id.* Petitioner's hearing test showed a profound left SNHL, with normal hearing in his right ear. *Id.* at 18. Dr. Kwartler diagnosed Petitioner with unspecified sudden hearing loss and hypoactive labyrinthine dysfunction. *Id.* He prescribed a Prednisone taper, discussed hyperbaric oxygen therapy, and ordered an MRI. *Id.*

Two days later, on November 5, 2014, Petitioner presented to the RWJ Center for Wound Healing for hyperbaric oxygen therapy. Ex. 16 at 1. He reported that he received "a flu shot at work [on] 10/21/2014 and stated he felt discomfort radiating up [the] left side of [his] neck and ear." *Id.* He also indicated that shortly after vaccination, he developed vertigo that initially lasted for five minutes and then dissipated on its own with severe dizziness. *Id.* He reported more episodes of vertigo the next day that were severe to the point of nausea and vomiting. *Id.* Petitioner stated that he felt like he was getting better, but still felt a little unbalanced. *Id.* The physician noted that Petitioner was "scheduled to have an MRI on Monday to make sure that there [wa]s no evidence of acoustic neuroma."⁶ *Id.* Petitioner received a trial of hyperbaric oxygen therapy at this visit and underwent a total of twenty-three hyperbaric oxygen treatments through December 15, 2014. *Id.* at 1, 51.

Additional Testing and Evaluation

A November 10, 2014 brain MRI performed on M.R. revealed a "round 5 mm x 4 mm structure in the distal aspect of the left internal auditory canal." Ex. 5 at 58. The neuroradiologist's impression was that the structure most likely represented a vestibular schwannoma. *Id.* Dr. Kwartler reviewed the MRI results with Petitioner on November 11, 2014.

⁵ That same day, Petitioner filed a Vaccine Adverse Event Reporting System ("VAERS") report, and reportedly contacted the pharmaceutical manufacturer of the vaccine, as well. Ex. 5 at 81; Ex. 12 at 1. VAERS is a database maintained by the Center for Disease Control ("CDC") to compile information from reports about reactions to immunizations listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a).

⁶ An acoustic neuroma, also known as vestibular schwannoma, is "a progressively enlarging, benign tumor, usually within the internal auditory canal arising from Schwann cells of the vestibular division of the eighth cranial nerve; the symptoms, which vary with the size and location of the tumor, may include hearing loss, headache, disturbances of balance and gait, facial numbness or pain, and tinnitus. It may be unilateral or bilateral." *Acoustic Neuroma*, Dorland's Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=92588> (last visited Oct. 3, 2022).

Ex. 9 at 13. Dr. Kwartler observed that the MRI showed “a left lateral internal auditory canal lesion consistent with an acoustic neuroma.” *Id.* at 14. His assessment was unilateral SNHL and acoustic neuroma. *Id.* Petitioner agreed to hold off on additional treatment until he had completed his hyperbaric oxygen therapy. *Id.* Dr. Kwartler added that if Petitioner did not recover, “it might be reasonable to proceed with a translabyrinthine approach for tumor removal” or, alternatively, repeat Petitioner’s “MRI in 6 months to monitor for any growth.” *Id.*

M.R. continued to see Dr. Goldrich for follow-up visits through December 2014 for steroid instillation into his external auditory canal. Ex. 5 at 19, 31, 36, 40. Dr. Goldrich first referenced Petitioner’s prior vaccination on November 6, 2014, noting Petitioner’s report that “[s]ymptoms began 4 days after receiving Flu Vaccine.” *Id.* at 36. On November 12, 2014, Dr. Goldrich noted that Petitioner had “acute hearing loss and vertigo following Influenza vaccination.” *Id.* at 33–34. During this visit he also noted that an MRI had revealed “a small acoustic neuroma on the left [side].” *Id.* at 31. By November 20, 2014, Petitioner was reportedly doing well, experiencing no vertigo or disequilibrium. *Id.* at 23. Dr. Goldrich noted that an audiogram conducted that day showed “some improvement in bone conduction levels on the left.” *Id.* However, a December 16, 2014, audiogram showed “no improvement in hearing on the left after 20+ treatments with hyperbaric oxygen.” *Id.* at 19.

On December 22, 2014, Petitioner filed an employee accident/illness report with RWJ, reporting that approximately five days after his vaccination he had developed episodes of vertigo and hearing loss. *Id.* at 88. He related his symptoms to vaccination. *Id.* The following day, on December 23, 2014, Petitioner underwent a hearing aid evaluation. *Id.* at 71. His medical history indicated that Petitioner “suspect[ed] that he lost his hearing in the left ear following administration of the flu shot.” *Id.*

On January 26, 2015, Petitioner returned to Dr. Kwartler to discuss hearing rehabilitation options. Ex. 9 at 10. In particular, they discussed a hearing aid—the attract bone-anchored hearing aid (“BAHA”) system⁷—and Dr. Kwartler ordered another MRI. *Id.* at 11. At his March 11, 2015, follow-up with Dr. Goldrich, Petitioner reported “stable symptoms of disequilibrium and hearing loss” and expressed an interest in pursuing a BAHA fitting. Ex. 8 at 23.

Another brain MRI was performed on April 9, 2015, and it showed an intracanalicular left vestibular schwannoma, but otherwise no changes from the first MRI (conducted on November 10, 2014). Ex. 14 at 86. On April 17, 2015, Dr. Kwartler surgically placed petitioner’s BAHA implant. Ex. 11 at 25. Petitioner had no complaints at his first post-operative visit six days later. Ex. 9 at 7. On May 11, 2015, he presented to Dr. Kwartler with a small amount of irritation along his incision, but this appeared to have cleared by May 27, 2015. *Id.* at 3, 5. He indicated to Dr.

⁷ In January 2015, Petitioner also tried a different hearing aid system, but had difficulty in the cafeteria and places with loud noise, so he returned the device. Ex. 13 at 9.

Goldrich at his June 23, 2015, follow-up visit that he had a BAHA fitting and was doing well, with no new complaints. Ex. 8 at 27–28. However, on July 20, 2015, he “[d]iscussed issues related to tissue change around the magnet” with Dr. Kwartler. Ex. 9 at 1.

Petitioner underwent a third brain MRI on September 24, 2015, and it (again) revealed “a left intracanalicular mass measuring 6 mm unchanged compared to prior MRI of 4/9/2015 which is consistent with vestibular schwannoma. . . .” Ex. 15 at 4. On October 5, 2015, Petitioner reviewed this MRI with Dr. Kwartler, who indicated that there was no change in his tumor size.” *Id.* at 2. Upon physical examination, Petitioner’s “[m]agnet site remain[ed] nicely healed,” his “cranial nerves intact,” and his “gait [was] steady.” *Id.* Dr. Kwartler’s diagnosed Petitioner with acoustic neuroma and unilateral SNHL. *Id.*

New Hearing Aid System and Continued Care

In November 2015, Petitioner expressed interest in switching to a new hearing aid system due to tissue build-up at his implant site that was interfering with magnet retention. Ex. 13 at 3. On November 19, 2015, Petitioner presented to otolaryngologist Kianoush Sheykholeslami, M.D. for an evaluation for a new hearing aid system. *Id.* Petitioner reported that he lost his left-sided hearing four days after a flu shot. *Id.* Dr. Sheykholeslami noted that there was “[n]o change in hearing sensitivity,” and recommended a follow-up to schedule the BAHA surgery. *Id.*

On December 17, 2015, Dr. Sheykholeslami revised Petitioner’s BAHA device. Ex. 14 at 8; Ex. 17 at 4. His preoperative and postoperative diagnoses remained unchanged as left unilateral deafness. Ex. 14 at 18. On December 24, 2015, Petitioner returned to Dr. Sheykholeslami, stating that he was doing very well. Ex. 17 at 2.

A repeat brain MRI was performed on March 31, 2016. As with the prior MRIs, it “reveal[ed] a 6 mm enhancing lesion in the left internal auditory canal . . . most consistent with a vestibular schwannoma.” Ex. 17 at 1. Several months later, Petitioner saw Dr. Kwartler on September 26, 2016, complaining of left ear pressure. Ex. 26 at 5. Dr. Kwartler advised continued monitoring of the acoustic tumor, which had not changed in size. *Id.*

On February 14, 2017, Petitioner saw audiologist Laura Matlin, Au.D., for an annual hearing evaluation. Ex. 21 at 1. Dr. Matlin documented Petitioner’s medical history, noting that in October 2014, “he reported a sudden hearing loss in the left ear 4 days following administration of the flu shot . . . A subsequent MRI revealed evidence of a ‘5 mm’ vestibular schwannoma in the left internal auditory canal.” *Id.* Upon examination, Petitioner exhibited normal hearing across all frequencies in his right ear and profound sensorineural hearing loss in his left ear. *Id.* Petitioner requested increased volume in his hearing aid. *Id.* Dr. Matlin recommended regular monitoring of

the left-sided vestibular schwannoma and annual audiologic exams to monitor petitioner's hearing. *Id.* at 2.

On July 3, 2018, Petitioner presented to his primary care provider ("PCP"), Dr. Brian Cassidy, for a comprehensive physical exam. Ex. 27 at 214. Dr. Cassidy noted:

Since I last saw [Petitioner] he had an[] acoustic neuritis culminating in the need for a BAHA procedure on the left by Dr. Kwartler. It was felt that it was related to an influenza immunization that he had been given and he has now gotten lifelong exemption for receiving further influenza immunizations.⁸

Id. A repeat brain MRI performed on April 25, 2019, showed a stable 6 mm vestibular schwannoma. *Id.* at 171.

On October 14, 2020, M.R. followed up with otolaryngologist P. Ashley Wackym, M.D., regarding his left vestibular schwannoma. Ex. 25 at 1. Dr. Wackym reviewed Petitioner's June 11, 2020 brain MRI, which showed a "small left distal vestibular schwannoma that extends to the fundus of his internal auditory canal." *Id.* Dr. Wackym also reviewed Petitioner's August 25, 2020 audiogram, which confirmed that Petitioner remained deaf in his left ear. *Id.* Dr. Wackym discussed cochlear implantation, but Petitioner stated that his tinnitus was not bothersome. *Id.* Dr. Wackym recommended a repeat MRI and audiogram in one year. *Id.* Petitioner has since had stable left-sided vestibular schwannoma, and his last documented MRI occurred in July 2021. Ex. 31 at 11–17.

II. Witness Testimony

A. M.R.

Petitioner was the only fact witness to testify. *See generally* Tr. at 5–23. His testimony largely consisted of his recollection of symptom onset and treatment.

Prior to vaccination, Petitioner stated, he was in good health, active, and had a normal social life. Tr. at 6. He never experienced hearing loss or vestibular symptoms. *Id.* at 15. On October 21, 2014, Petitioner received the flu vaccine as a suggestion of a co-worker.⁹ *Id.* at 7. He described the vaccination as "pretty much painless." *Id.* at 7. The following day he developed

⁸ Dr. Cassidy *did* recommend other vaccinations, however, including for tetanus, diphtheria, and pertussis, pneumonia, and shingles. Ex. 27 at 37. And during a February 16, 2021 visit, he "strongly advised [receipt of] the COVID vaccine." *Id.* at 8.

⁹ In 2014, Petitioner was not required to get the flu shot for his job as a registered nurse. Tr. at 7, 21. As of the date of the hearing, Petitioner noted that it was required by his job, but he had a lifetime exemption granted by treaters due to his purported reaction from the flu vaccine at issue in this case. *Id.* at 16, 22.

soreness at the injection site, and over the next four days he described the pain as travelling up his shoulder, to his neck, and eventually to his left ear. *Id.* at 7–8.

He began experiencing symptoms related to his hearing loss on October 25, 2014—four days post-vaccination—when he noticed sound becoming distant in his left ear followed by a sudden onset of vertigo lasting four to five minutes before clearing up.¹⁰ Tr. at 8. The next day, he had two similar episodes of hearing loss in his left ear followed by vertigo, which lasted between three to five minutes before clearing up. *Id.* at 8.

On the morning of October 27, 2014, Petitioner had another episode of hearing loss in his left ear followed by vertigo, but it did not dissipate as it had previously.¹¹ Tr. at 8. That morning he arrived at work, but was instructed by his supervisor to go to the ER. *Id.* at 9. At the ER he underwent a CAT scan to rule out a tumor or stroke, and was referred to an ear, nose, and throat specialist (Dr. Goldrich) who sent him for a myringotomy tube to distribute steroids, and in turn referred him to a neurotologist (Dr. Kwartler). *Id.* at 9–10. Dr. Kwartler increased Petitioner’s steroids, recommended hyperbaric oxygen therapy,¹² and ordered an MRI. *Id.* at 10. The MRI found a small vestibular schwannoma or acoustic neuroma on the left side. *Id.* at 11.

Petitioner returned to work after three and a half to four weeks, but continued to experience vertigo. Tr. at 12. Following his return, he attended hyperbaric oxygen therapy three times a week for four to five weeks, and continued with steroids until the course was finished. *Id.* At that point, Petitioner’s hearing in his left ear had not yet returned. *Id.*

As traditional hearing aids do not work for Petitioner’s type of hearing loss, he currently uses a BAHA. Tr. at 12. He developed a pressure ulcer or bedsore due to the BAHA Attract¹³ and had to change to a “Connect”¹⁴ device. *Id.* at 13. Petitioner filed a workers compensation claim due to his hearing loss and vertigo, which was denied as it was not a covered problem, and he did not file an appeal. *Id.* at 21.

¹⁰ In M.R.’s affidavit he stated that his vertigo lasted about two minutes rather than four to five minutes. M.R. Affidavit at 2.

¹¹ By this point, Petitioner’s vertigo did not go away for three to four weeks, and he lost all hearing in his left ear. Tr. at 8, 11.

¹² Petitioner described the hyperbaric oxygen therapy as a 60-90 minute session where he was in a pressurized container brought down to two atmospheres at 100 percent oxygen, and slowly brought back up. Tr. at 11.

¹³ Petitioner described the Attract as a small screw placed into the mastoid bone behind the ear attached by a magnet. Tr. at 13. The device would attach to the outside of the magnet and the sound was transmitted from the device into the bone, and is picked up by the right ear. *Id.* Petitioner wore this device about 16 hours a day, and the constant pressure of the magnet caused the pressure ulcer or bedsore. *Id.*

¹⁴ The Connect does not use a magnet, but has an abutment post that protrudes through the skin where the device connects. Tr. at 13. Petitioner did not originally opt for the Connect because the skin was not totally closed, and in his role as a registered nurse he has patients with infections, but later determined the risk was low. *Id.* at 14, 22.

Petitioner is now single-sided deaf on the left side and continues to experience vertigo if he turns quickly or closes his eyes. Tr. at 14–15. Other than some age-related hearing loss, his right ear is normal and he is in normal health. *Id.* at 19. He was initially getting an MRI every six months, but reduced the frequency to once a year, and is planning to reduce it again to once every two years because there is no growth of his tumor noted on the MRI. *Id.* at 15, 21. He also visits his hearing specialist treaters, and undergoes an audiology exam, once a year. *Id.* at 15.

M.R. testified that he has had some difficulties and concerns in daily life due to his hearing loss. He does not have sound localization due to the lack of stereo hearing, but has learned to accommodate this. Tr. at 16. Even with the BAHA, Petitioner can only receive 50 percent of sound on his left side which makes him more cautious while driving. *Id.* at 17. In a professional setting, he must position himself with his right ear toward whoever he is having a conversation with—especially while performing a procedure with a physician, and there is some difficulty when using a stethoscope. *Id.* Petitioner can no longer scuba dive, and he finds it difficult to hear in noisy environment, which has impacted his social life. *Id.* at 18. He has concerns for the future as his insurance does not cover the cost of replacing the BAHA (approximately \$5,000) and they tend to wear out every four to five years. *Id.* at 18–19. Petitioner is looking into getting a cochlear implant. *Id.* at 19–20.

B. Petitioner's Expert – Edwin Monsell, M.D., Ph.D.

Dr. Monsell, an otolaryngologist, submitted two expert reports and testified for the Petitioner in support of the contention that the flu vaccine can cause SNHL. *See generally* Tr. at 24–104, 151–58; Report, dated Feb. 27, 2017, filed as Ex. 22 (ECF No. 24-1) (“Monsell First Rep.”); Report, dated Jan. 21, 2022, filed as Ex. 24 (ECF No. 70-1) (“Monsell Second Rep.”).

Dr. Monsell attended Williams College for his undergraduate degree in biology. *See* Curriculum Vitae, dated Feb. 27, 2017, filed as Ex. 23 (ECF No. 24-2) (“Monsell CV”) at 1; Tr. at 24. He also attended Duke University for his doctorate in cell biology and neuroscience, and the University of North Carolina School of Medicine for his medical degree. Monsell CV at 1; Tr. at 24, 32–33. He then completed his business degree from Oakland University. Monsell CV at 1; Tr. at 26. For over 20 years, Dr. Monsell has served as a Director and Professor Emeritus of Otolaryngology—Head and Neck Surgery at Wayne State University. Monsell CV at 1; Monsell First Rep. at 1; Tr. at 27. He has maintained an active practice in otology and neurology for over 30 years, treated thousands of patients with hearing loss, and performed over 3,500 major ear operations to remove tumors, infection, and restore hearing. Monsell First Rep. at 1; Tr. at 107, 110. He is board certified in otolaryngology and neurotology. Monsell First Rep. at 1; Monsell CV at 4; Tr. at 26. He has also published literature specifically on vestibular schwannoma and has around 85 peer-reviewed papers, case reports, and book chapters. Tr. at 30.

Dr. Monsell began with a summary of the medical records, reiterating M.R.’s prior testimony. Tr. at 33–35; Monsell First Rep. at 1–2. He then opined on Petitioner’s diagnosis,

explaining that he had sudden SNHL in the left ear, vertigo, and tinnitus (although the latter symptom was delayed in its onset). Tr. at 35. In embracing this diagnosis, Dr. Monsell relied on the medical records and Petitioner's treating physicians, who consistently diagnosed Petitioner with SNHL. *Id.* at 37. He also assessed the possibility of Petitioner obtaining a cochlear implant and the role of vestibular schwannoma as a cause of hearing loss, maintaining that the prescribing doctor would need to be sure that the cochlear nerve was active and functional. *Id.* at 151–55.

Dr. Monsell described some of the relevant medical concepts bearing on Petitioner's claim. SNHL, he explained, is generally defined as hearing loss that develops over a 72-hour period, with thresholds worsening by 30 decibels or more in three or more contiguous octave intervals. Tr. at 36; Monsell First Rep. at 2. He distinguished SNHL from comparable conditions, such as age-related hearing loss and noise-reducing hearing loss, which tend to develop gradually over years. Tr. at 36. Importantly, Dr. Monsell admitted that the causal sequence in sudden SNHL is not yet known. Monsell Second Rep. at 1.

Dr. Monsell also attempted to explain a vestibular schwannoma, maintaining overall that while a schwannoma could be related to SNHL, it amounted only to a risk factor as opposed to a direct causal element.¹⁵ Tr. at 62–63, 70–72. A vestibular schwannoma, Dr. Monsell explained, is a tumor of cells that grow on the vestibular (or hearing balance) nerve. *Id.* at 63; Monsell First Rep. at 4–5. They are also called acoustic neuromas. Tr. at 91.¹⁶ A vestibular schwannoma can result in a slow, progressive or more rapid hearing loss. *Id.* at 63; Monsell Second Rep. at 4; A. Aslan et al., *Clinical Observations on Coexistence of Sudden Hearing Loss and Vestibular Schwannoma*, 117 Otolaryngology – Head & Neck Surgery 580, 580 (1997), filed as Ex. 24, Tab A (ECF No. 70-2) (“Aslan”).¹⁷

Vestibular schwannomas can exist without symptoms, and thus are sometimes discovered as an incidental finding—such as when trying to understand the etiology of a patient's headaches. Tr. at 65. Dr. Monsell agreed, however (and somewhat contrary to his prior contention that acoustic neuromas were not always themselves causal of hearing loss), that the possibility of an acoustic neuroma should be considered in all patients presenting with asymmetric SNHL or with other persistent unilateral or asymmetric ear symptoms. *Id.* at 91. Treatment includes steroids

¹⁵ Other risk factors included hypertension and severe obesity. Tr. at 71, 84. One study noted that hypertension was more prevalent in a group of subjects with sudden SNHL, but no difference was found in the prevalence of personal cardiovascular risk factors (e.g., hypertension, diabetes, hyperlipidemia, or smoking) in 96 patients with sudden SNHL versus 190 age and gender-matched controls. Monsell First Rep. at 5; I. Mosnier et al., *Cardiovascular and Thromboembolic Risk Factors in Idiopathic Sudden Sensorineural Hearing Loss: A Case-Control Study*, Audiology & Neurotology 55, 62–64 (2011), filed as Ex. 22, Tab S (ECF No. 67-9). Dr. Monsell also suggested that the flu vaccine might have heightened importance for high-risk individuals, though he argued Petitioner was probably more at risk due to his own obesity or hypertension. Tr. at 71, 84.

¹⁶ Both terms shall be used interchangeably in this Decision.

¹⁷ Also filed as Respondent's Ex. A, Tab 7. (ECF No. 29-8).

administered intratympanic or orally, and hyperbaric oxygen. *Id.* at 69–70; Monsell First Rep. at 5. Dr. Monsell admitted that medical science could at this point only speculate about how an acoustic neuroma might manifest and in turn cause SNHL. Tr. at 65. He also did not deny that there is a statistical and probably causal relationship between sudden SNHL and the discovery of an existing vestibular schwannoma in the relevant individual. *Id.* at 91–92; Monsell Second Rep. at 3.

During his testimony, Dr. Monsell went into great detail as to how the ear works, relying on a diagram to do so. Tr. at 37–42; Trial Ex. 1. He discussed the cochlea—the inner ear—and explained how its many functions are connected. Tr. at 38. The neural tissues of the inner ear are encased in hard bone. *Id.* The cochlea of the inner ear is coiled up, and the area across the spiral is the basilar membrane, which vibrates with the frequency of sound. *Id.* at 39. The hair cells are the auditory receptors, which convert vibrations of sound into nerve impulses. *Id.* These hair cells then bend and mechanically open ion gates, letting in calcium and potassium. *Id.* at 40. There are two chambers that contain high potassium solution, called the scala vestibuli perilymph and scala tympani perilymph. *Id.* at 38. Additionally, the scala media has endolymph, which is also high in potassium. *Id.* The difference between these chambers is created and maintained by the stria vascularis, which has many blood vessels to provide necessary oxygen and nutrients (and is where the immune-mediating processes have been localized with immunohistochemistry). *Id.* at 38–39, 42. The opening of the ion gates leads to an electrical change in the hair cells, which is picked up at the bottom of the hair cell by the dendrites of the auditory neurons through the synaptic connection. *Id.* at 40.

Dr. Monsell also described the interplay between the inner ear and inflammation. The cochlea is metabolically active, so the stria vascularis and the outer and inner hair cells are responsible for shunting potassium. Tr. at 42–43; Monsell First Rep. at 5; D. R. Trune, *Ion Homeostasis and Inner Ear Disease*, Medical Otology and Neurotology 21, 24 (2006), filed as Ex. 22 Tab, FF (ECF No. 69-2) (“Trune”) (showing the path of potassium recycling). Any form of labyrinthitis (inner ear inflammation) could compromise the ion hemostasis, which is crucial for the function of hearing, by effects on the vasculature of the cochlear lateral wall and stria vascularis. Tr. at 42; Monsell First Rep. at 5; Monsell Second Rep. at 4; Trune at 21. This can often affect the balance function of the inner ear as well. Tr. at 42. However, the inner ear has its own local system for dealing with inflammation. *Id.* at 43–44; M. Fujioka et al., *Inflammatory and Immune Responses in The Cochlea: Potential Therapeutic Targets for Sensorineural Hearing Loss*, 5 Frontiers Pharmacology 1, 1–3 (2014), filed as Ex. 2, Tab J (ECF No. 66-10) (“Fujioka”). For example, macrophages, which are immune surveillance cells, wind their processes through the hair cells and the spiral ligaments and constantly monitor the inner ear for inflammation. Tr. at 43–44; Fujioka at 3.

Next, Dr. Monsell proposed a causal mechanism for sudden SNHL: the stress response theory. Tr. at 45. At the outset, he noted difficulty in studying the inner ear, which made it hard to provide more definitive reliable support for the theory, and there was otherwise no solid proof of this mechanism, but that the concept did find some support in the scientific/medical community. *Id.* at 45, 50–51, 73, 83; M. Masuda & J. Kanzaki, *Cause of Idiopathic Sudden Sensorineural Hearing Loss: The Stress Response Theory*, 3 *World J. Otorhinolaryngology* 42, 50 (2013), filed as Ex. 29 (ECF No. 53-1) (“Masuda”) (addressing potential immune reactant as a stimulation, but not addressing the flu vaccine specifically nor acoustic neuromas); S. Merchant et al., *Pathology and Pathophysiology of Idiopathic Sudden Sensorineural Hearing Loss*, 26 *Otology & Neurotology* 151, 158–59 (2005), filed as Ex. 24, Tab G (ECF No. 70-8) (“Merchant”).

Dr. Monsell deemed Merchant to provide particularly good support for how the stress response theory could explain vaccine-induced SNHL. Tr. at 45–46. Merchant’s authors engaged in a postmortem evaluation of human temporal bones in the ear, and they did not conclude that viral infection alone could be causal of sudden SNHL. *Id.* at 46; Merchant at 158–59. However, Merchant hypothesized that sudden SNHL was most likely the result of activation of cell stress pathways involving the nuclear factor kappa beta (“NF- κ B”), the master immune complex that regulates inflammation and responds to injury in the tissue. Tr. at 46, 82; Monsell First Rep. at 5; *but see* Merchant at 158 (noting that none of the studied patients had acoustic neuromas).

Merchant specifically speculated that sudden SNHL might reflect the end-result of rapid progression of events after NF- κ B activation. Tr. at 47; Monsell Second Rep. at 1; Merchant at 158–59. SNHL’s unilateral character was echoed by animal studies demonstrating that NF- κ B was also activated mainly in one ear. Tr. at 47; Monsell Second Rep. at 1; Merchant at 158–59. One particular animal study (which localized messenger RNA for several inflammatory factors)¹⁸ provided more details about how the NF- κ B activation might occur. Tr. at 48; Monsell Second Rep. at 1; J. Adams, *Clinical Implications of Inflammatory Cytokines in the Cochlea: A Technical Note*, 23 *Otology & Neurotology* 316, 317–20 (2002), filed as Ex. 24, Tab B (ECF No. 70-3) (“Adams”). Adams proposed that SNHL associated with NF- κ B could be explained by the disruption of the normal balance of inflammatory cytokines, and thus that a systemic challenge elsewhere in the body could theoretically stimulate the immune system in the inner ear (though Adam’s authors admitted that, given the sparse experimental evidence to support this contention, the contention remained speculative).¹⁹ Tr. at 49–50, 81–82; Monsell Second Rep. at 1; Adams at 321; J. C. Adams et al., *Selective Activation of Nuclear Factor Kappa B in the Cochlea by Sensory*

¹⁸ Dr. Monsell also mentioned IL-6, one of the key cytokines produced by the activation of NF- κ B- and that has the ability to create positive feedback so it can be released by NF- κ B and then in turn stimulate NF- κ B. Tr. at 51.

¹⁹ On cross examination, Dr. Monsell also addressed articles he cited regarding the flu virus proteins having been shown to stimulate NF- κ B in the immune system. Tr. at 80–81. He admitted that these articles all focused on the flu virus infection, as opposed to the vaccine, and acknowledged that infection and vaccination are different, but argued that what was known about the wild infectious process could be used as a model. *Id.*

And Inflammatory Stress, Neuroscience 530, 536 (2009), filed as Ex. 24, Tab C (ECF No. 77-1) (“Adams & Seed”).

Dr. Monsell then attempted to demonstrate how the flu vaccine in particular could, via the stress response theory, cause SNHL in an individual.²⁰ Tr. at 51–53; Monsell Second Rep. at 1; *see generally* Adams & Seed at 536–38 (describing how this mechanism works in an animal model). Administration of the vaccine would, he proposed, cause an increase in circulating cytokines of several kinds, including IL-6 and interleukin-6. Tr. at 52. In support, Dr. Monsell referenced an article that describes the inflammatory response after flu vaccination, and the kinds of humoral cells that the vaccine can cause to be released or increased. *See, e.g., Id.* at 52, 102–04; Monsell First Rep. at 5; C. Carty et al., *Inflammatory Response After Influenza Vaccination in Men with and Without Carotid Artery Disease, Arteriosclerosis, Thrombosis, & Vascular Biology* 2738, 2741–43 (2006), filed as Ex. 30 (ECF No. 53-2) (“Carty”); P. Liuba et al., *Cause of Idiopathic Sudden Sensorineural Hearing Loss: The Stress Response Theory*, Annals Med. 392, 397–98 (2007), filed as Ex. 22, Tab Q (ECF No. 67-7) (“Liuba”) (demonstrating inflammation following the administration of the flu vaccine in humans, but noting that the relatively low number of individuals in the study and short duration of follow-up preclude definitive conclusions regarding the significance of their findings). Despite its admitted limitations, Liuba showed (in Dr. Monsell’s estimation) that the flu vaccine can result in a mild, measurable, acute phase reaction. Tr. at 52. And Carty revealed how the flu vaccine causes an immediate increase in IL-6—a cytokine known to stimulate NF- κ B. *Id.* at 52; Carty at 2739–41. Carty thus allowed for the possibility of NF- κ B stimulation in the ear, as well—even if the article literally did not discuss hearing loss whatsoever. Tr. at 78–80.

In addition to seeking to bulwark his mechanistic theory, Dr. Monsell attempted to respond to certain items of epidemiologic literature, which had found no association between the flu vaccine and high rates of sudden SNHL. Tr. at 56, 76; R. Baxter et al., *Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis*, 115 Otolaryngology – Head & Neck Surgery 81, 84–85 (2016), filed as Ex. 22, Tab B (ECF No. 66-2) (“Baxter”) (no statistically significant association between sudden SNHL and receipt of other vaccinations, including the flu vaccine, out of eight million patients in sample).²¹ Dr. Monsell generally questioned Baxter’s

²⁰ Dr. Monsell denied that variability in immune responses in individuals impacted the validity of his proposed stress response mechanism. Tr. at 58–59; C. Thomas & M. Moridani, *Interindividual Variations in the Efficacy and Toxicity of Vaccines*, Toxicology 204, 207, 209 (2010), filed as Ex. 22, Tab EE (ECF No. 69-1) (offering the hypothesis that adverse reactions may not be random but partly genetically determined, so no two individuals will respond in the exact same way). Additionally, Dr. Monsell addressed anatomical asymmetry, pre-existing cochlear injury, and genetic factors, with one study observing that various forms of stress, challenges, and dysregulation could impact cochlear ischemia and increase cytokine production. Tr. at 59–60; Masuda at 49–50. However, he could not point to evidence of genetic susceptibility for Petitioner to adverse events from vaccination. Tr. at 86–87.

²¹ Also filed as Respondent’s Ex. A, Tab 8. (ECF No. 29-9).

methodologic reliability.²² For example, he pointed to its Table 2, which identified a risk interval of 1 to 14 days with an odds ratio of 1.235. Tr. at 56; Baxter at 84. There were 92 cases of hearing loss occurring within the 14-day risk interval, and when Baxter's authors compared the two groups (vaccinated versus unvaccinated), the odds ratio did not favor an association. Tr. at 56. Dr. Monsell stated that the standard statistical criterion for significance is a "P value" ²³ less than 0.05, so the odds ratio in this case did not permit high confidence in the findings (even if they did not facially favor an association). *Id.* at 56–57. Thus, despite Baxter's overall conclusion, Dr. Monsell denied that it excluded any vaccine association. *Id.* at 58. On cross examination, however, Respondent noted that M.R.'s onset had actually occurred within the shorter risk interval of 1-7 days, and that Baxter not only considered the odds ratio for this period as well but (unlike the expanded 1-14 day period) *did* find a statistically-significant lack of association for the shorter timeframe—a point Dr. Monsell did not persuasively rebut. *Id.* at 76–77; Baxter at 84.

In addition, there was a related deficiency in Dr. Monsell's opinion—since much of the literature he relied upon involved wholly distinguishable vaccines, rather than the inactivated flu vaccine. Tr. at 73–76; Monsell First Rep. at 2–3; A. Asatryan et al., *Live Attenuated Measles and Mumps Viral Strain-Containing Vaccines And Hearing Loss: Vaccine Adverse Event Reporting System (VAERS), United States. 1990-2003*, Vaccine 1166, 1170–71 (2008), filed as Ex. 22, Tab A (ECF No. 66-1) ("Asatryan")²⁴ (suggesting that it was biologically possible that hearing loss could be causally associated with the measles and mumps vaccine given that they contain the live-attenuated strains of the viruses (not discussing the inactivated version of the flu vaccine relevant in this case)). Other studies only addressed the effect of different kinds of wild infections. See, e.g., M. McKenna, *Measles, Mumps, and Sensorineural Hearing Loss*, Annals N.Y. Acad. Sci. 291, 296–97 (1997), filed as Ex. 22, Tab R (ECF No. 67-8) (studying measles and mumps and SNHL); R. Veltri et al., *The Implication of Viruses in Idiopathic Sudden Hearing Loss: Primary Infection or Reactivation of Latent Viruses?*, Otolaryngology – Head & Neck Surgery 137, 140 (1981), filed as Ex. 22, Tab JJ (ECF No. 69-6) (focusing on a theory of reactivation and infectious agents (such as an actual infection as opposed to vaccination)); W. Wilson et al., *Viral and Epidemiologic Studies of Idiopathic Sudden Hearing Loss*, 91 Otolaryngology – Head and Neck

²² Dr. Monsell also questioned whether Baxter was sufficiently powered to yield reliable results. Tr. at 77; Monse I Second Rep. at 2. However, on cross examination it was pointed out that power was actually dependent on the number of vaccines administered and then considered in the study. Tr. at 77–78; Baxter at 85. Even though Baxter's authors forthrightly concluded that their findings of a lack of vaccine association were quite robust, given the eight million flu vaccine doses considered, Dr. Monsell maintained that the possibility that the flu vaccine could cause sudden SNHL could not be excluded, even in such a large sample. Tr. at 78; Baxter at 85; Monsell First Rep. at 3–4; Monsell Second Rep. at 2.

²³ The P value is defined as "the probability of obtaining by chance a result at least as extreme as that observed, even when the null hypothesis is true and no real difference exists; when $P \leq 0.05$ the sample results are usually deemed significant at a statistically important level and the null hypothesis rejected." *P value*, Dorland's Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=116692> (last visited Oct. 3, 2022).

²⁴ Also filed as Respondent's Exhibit A, Tab 10.

Surgery 653, 656 (1983), filed as Ex. 22, Tab LL (ECF No. 69-8) (centering on viral infections as opposed to vaccination). And some articles involved experiments involving direct stimulation of the ear, as opposed to the systemic impact of vaccination administered elsewhere in the body. L. Davis, *Comparative Experimental Viral Labyrinthitis*, Am. J. Otolaryngology 382, 387 (1990), filed as Ex. 22, Tab G (ECF No. 66-7) (using inner ear or intranasal inoculation in an animal study, which was not how Petitioner received the vaccine in this case). Ultimately, Dr. Monsell acknowledged that he could not identify any paper that specifically addressed the situation of patients with acoustic neuromas who also received the flu vaccine, and whether the two might have any synergistic interaction. Tr. at 98. He also was not aware of medical literature that indicated whether a patient with an acoustic neuroma was more susceptible to sudden SNHL after receiving the flu vaccine. *Id.* at 98.

The vestibular schwannoma that Petitioner was discovered to possess did not alter Dr. Monsell's opinion regarding the medical reliability of his proposed mechanism of sudden SNHL. Tr. at 53–54; Monsell Second Rep. at 2–3. He agreed that literature suggested an association. *See, e.g.*, J. Saunders et al., *Sudden Hearing Loss in Acoustic Neuroma Patients*, 113 Otolaryngology – Head & Neck Surgery 23, 30–31 (1995), filed as Ex. 24, Tab M (ECF No. 71-4) (“Saunders”)²⁵ (considering what might cause sudden hearing loss in the setting of vestibular schwannoma). Saunders, one of the larger studies specific to the question, considered 13 patients and concluded that it was possible that vestibular schwannoma may predispose the cochlear system to a biomechanical change, such as a membrane rupture (although no evidence of a membrane rupture was found in its sample). Tr. at 54; Saunders at 30–31. But Saunders also discussed 79 acoustic neuroma patients treated at the author's clinic, all of whom had well-documented sudden SNHL as their initial symptom (ranging from mild to profound). Tr. at 97; Saunders at 26. Although Dr. Monsell admitted that Saunders established the existence of variation for hearing loss in the context of an acoustic neuroma, he argued that rarely can a tumor alone be causally associated with SNHL in the absence of other factors, like an inflammatory milieu. Tr. at 97–98; Monsell First Rep. at 5; Monsell Second Rep. at 2–3.

Dr. Monsell thus deemed Petitioner's acoustic neuroma not likely causative of his SNHL. In his view, the nature of Petitioner's SNHL was not consistent with half the cases involving vestibular schwannoma present with sudden SNHL,²⁶ (although this also meant that it was consistent with the other half). Tr. at 64, 69–71, 93–94; Monsell Second Rep. at 2–3. Dr. Monsell also alleged that Petitioner's tumor was too small to have caused the severe²⁷ level of hearing loss

²⁵ Also filed as Respondent's Ex. A, Tab 5. (ECF No. 29-6).

²⁶ Inconsistencies with symptoms included Petitioner's presentation of acute vertigo, but Dr. Monsell acknowledged clinical presentations can vary. Tr. at 96–97; Monsell First Rep. at 5. He also agreed that patients with acoustic neuromas sometimes do not find steroid treatments effective. Tr. at 97.

²⁷ The severity was, in Dr. Monsell's view, obvious from Petitioner's medical records—specifically, M.R.'s audiologic findings from an October 30, 2014 visit reporting that the outer hair cells in the left ear had no response.

present, leaving the flu vaccine as the exclusive cause of Petitioner's injury. Tr. at 64, 69–71, 100. On cross examination, Respondent noted poor scientific or medical correlation between the level of hearing loss and the size of the tumor, but Dr. Monsell maintained that most correlational studies do not measure a tumor as small as Petitioner's, so the studies cannot be applied in the same way (although he could not cite any independent evidence for this contention). *Id.* at 94–96.

Petitioner's medical history was, in Dr. Monsell's reading, supportive of the conclusion that the flu vaccine had most likely caused his sudden SNHL. Tr. at 60, 70–72; Monsell First Rep. at 6. Prior to vaccination, M.R. was in excellent general and neurologic health, and had no problems with his hearing or balance prior to vaccination. Tr. at 60–61. Even if Petitioner had already possessed a vestibular schwannoma pre-vaccination, lowering the threshold for cochlear damage, Dr. Monsell could not find evidence of any alternative cause for Petitioner's SNHL other than vaccination. *Id.* at 61, 71.²⁸ He also maintained that the medical record consistently referenced Petitioner's vaccination in relation to his hearing loss. *Id.* at 61.

Dr. Monsell also attempted to address the fact that M.R. had received the flu vaccine in several prior years without any adverse effect. Tr. at 87. It was possible, Dr. Monsell argued, that Petitioner could have been exposed to antigens throughout but that he only reacted to after the “last” dose, and there was the inherent variability of immune responses due to age and environmental factors to take into account, as well. *Id.* at 87, 101; Ex. 12 at 15. Thus, Dr. Monsell maintained that the stress response theory was still applicable despite the lack of adverse effects after previous vaccinations. Tr. at 87. However, Dr. Monsell acknowledged that aside from a local reaction, the record revealed no evidence of any objective markers of inflammation around the time of hearing loss onset. *Id.*; Monsell Second Rep. at 1. Petitioner also did not undergo the type of testing that would demonstrate inflammation. Tr. at 87–88. And though Dr. Monsell argued that inflammation could be potentially inhibited by steroids (and thus theoretically receipt of steroids could mask an inflammatory background), Petitioner in this case did not even see therapeutic benefit from the steroid treatments he received (something Dr. Monsell argued was simply further proof of the severity of his injury). *Id.* at 88–89.

Finally, Dr. Monsell opined that Petitioner's onset of symptoms (four days after vaccination) was a medically appropriate timeframe in which the proposed inflammatory mechanism would occur. Tr. at 71. Hearing loss symptoms could, under Dr. Monsell's theory,

Tr. at 66–67; Ex. 8 at 11. Another visit on November 20, 2014, stated in the audiogram and otoacoustic emissions (another type of auditory test) report that the left ear was not responding at all. Tr. at 65–69; Ex. 8 at 6–7.

²⁸ For example, the medical record established that Petitioner's medical providers had recommended an MRI—the gold standard of diagnostic test for an acoustic neuroma. Tr. 91, 93. When Petitioner first presented to the ER on October 27, 2014, the attending physician noted that potential diagnosis included a cerebellopontine angle (“CPA”) tumor (a type of acoustic neuroma). *Id.* at 93; Ex. 7 at 113–15. However, Petitioner's treatment course did not change as a result of his MRI, and there were no additional treatments recommended, even after the MRI revealed the vestibular schwannoma. Tr. at 100.

occur as early as one day, but typically would take a few days to manifest, and could happen even a few weeks afterward. *Id.* at 71–72. In support of this assertion, he cited Baxter, which observed 92 cases of hearing loss within the first 14 days of vaccination, and three occurring within a week. *Id.* at 72; Monsell First Rep. at 6; Baxter at 84. He also cited to Carty, which showed vaccine stimulation of IL-6 upregulation still strong at 24-hours post-vaccination, indicating these processes are cascades and there is variability within the ranges discussed. Tr. at 72; Carty at 2741–42.

C. Respondent's Expert – Douglas Bigelow, M.D.

Dr. Bigelow, an otolaryngologist, testified on behalf of Respondent, and submitted two expert reports. *See generally* Tr. at 106–51; Report, dated May 17, 2017, filed as Ex. A (ECF No. 29-1) (“Bigelow First Rep.”); Report, dated Sept. 14, 2017, filed as Ex. C (ECF No. 34-1) (“Bigelow Second Rep.”). Dr. Bigelow disputed the flu vaccine’s role in causing hearing loss.

Dr. Bigelow attended Hamline University for his undergraduate degree in chemistry. *See* Curriculum Vitae, dated May 18, 2017, filed as Ex. B (ECF No. 30-3) (“Bigelow CV”) at 1. He then attended the University of Minnesota School of Medicine for his medical degree. Bigelow CV at 1; Tr. at 106. He is currently an Associate Professor in the Department of Otorhinolaryngology: Head and Neck Surgery at the University of Pennsylvania School of Medicine and the Director of the Division of Otology and Neurotology at the University of Pennsylvania Medical Center. Bigelow CV at 2; Tr. at 107. He has over 25 years of experience as an attending physician managing patients with otology problems, including hearing loss, dizziness, and acoustic neuromas. Bigelow First Rep. at 11. He has lectured extensively on hearing loss, dizziness, and acoustic neuromas, and has co-authored at least forty peer-reviewed publications. Bigelow CV at 5–18; Tr. at 108–09. He is also board certified in otolaryngology and neurotology. *Id.* at 2; Bigelow First Rep. at 11; Tr. at 107.

Dr. Bigelow began with a background summary of sudden SNHL. Tr. at 110–14. SNHL typically presents as sudden or rapid hearing loss occurring over a number of hours to a period of days, with some patients also experiencing dizziness. *Id.* at 110–11. Dr. Bigelow stated that there is not typically an inciting event, though some patients have been known to have experienced upper respiratory symptoms beforehand. *Id.* at 111; Bigelow First Rep. at 10. SNHL is, in Dr. Bigelow’s view, somewhat common; a 2013 study, for example, determined there are over 66,000 new cases in the U.S. every year. Tr. at 111; Bigelow First Rep. at 8; T. Alexander & J. Harris, *Incidence of Sudden Sensorineural Hearing Loss*, *Otology & Neurotology* 1586, 1587–88 (2013), filed as Ex. A, Tab 1 (ECF No. 29-2) (“Alexander & Harris”).

Though there is no particular demographic of people that most commonly experience SNHL, it occurs more frequently in older patients. Tr. at 112; Bigelow First Rep. at 8; Alexander & Harris at 1588 (noting that 70 per 100,000 patients over 65 experienced sudden hearing loss,

whereas approximately 27 per 100,000 patients under 65 experienced the phenomenon). For the majority of SNHL patients, no etiology is ever identified. Tr. at 126; Bigelow First Rep. at 8. Sudden hearing loss is typically diagnosed by an audiogram, and other tests may be ordered, like blood work or an MRI scan to evaluate for the presence of an acoustic neuroma or other tumors. Tr. at 112–13. Treatment focuses on steroids, and occasionally patients also use hyperbaric oxygen. *Id.* at 113. Patients typically have total or partial improvement after steroids, but that is not always the case. *Id.*

Dr. Bigelow next described acoustic neuroma, identifying it as a common cause of sudden hearing loss. Tr. at 118–19, 121–22, 130; Bigelow First Rep. at 8; Bigelow Second Rep. at 5. While he acknowledged that acoustic neuromas were not *themselves* common, he did not agree with Dr. Monsell’s characterization that they were exceedingly rare (and in any event, the point was irrelevant—since it cannot be disputed that *Petitioner* had in this case experienced one). Tr. at 131, 132; Bigelow First Rep. at 9. A neuroma is a benign tumor growing from the Schwann cells.²⁹ Tr. at 118. Typically, the growth occurs on the vestibular portion of the eighth cranial nerve, which controls hearing and balance. *Id.* at 118–19. The tumor can grow slowly over a period of years as evidenced by monitoring serial scans. *Id.* at 119. The classic clinical presentation associated with the existence of an acoustic neuroma is progressive hearing loss that is associated with vertigo and ringing noises, pressure, and fullness in the affected ear.³⁰ *Id.* at 121, 145. He also noted that an acoustic neuroma does not require a triggering factor, such as inflammation, to cause hearing loss, and it is otherwise unknown why the neuroma would precipitate such loss. *Id.* at 132, 144–45; Bigelow Second Rep. at 5.

Dr. Bigelow surmised that anywhere from 3–20 percent of acoustic neuroma patients experience sudden hearing loss, making them at high risk for SNHL.³¹ Tr. at 130–31, 145–46; Bigelow First Rep. at 9; Bigelow Second Rep. at 5, 8; D. Moffat et al., *Sudden Deafness in Vestibular Schwannoma*, *J. Laryngology & Otology* 116, 117 (1994), filed as Ex. C, Tab 1 (ECF

²⁹ Schwann cells are “any of the large nucleated cells whose cell membrane spirally enwraps the axons of myelinated peripheral neurons and is the source of myelin; a single Schwann cell supplies the myelin sheath between two nodes of Ranvier.” *Schwann Cell*, Dorland’s Medical Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=64407&searchterm=Schwann+cell> (last visited Oct. 3, 2022).

³⁰ Dr. Bigelow’s citation to Saunders—an article stating that vestibular symptoms were not usually present in SNHL patients with acoustic neuroma—was raised in cross-examination questioning. Tr. at 146–47; Bigelow First Rep. at 8–9; J. Saunders at 8. But Dr. Bigelow argued in response that it is understood that vestibular symptoms *can* be present with an acoustic neuroma, regardless of whether SNHL is also evident. Tr. at 146; Bigelow Second Rep. at 5–6. He also disputed Saunders’s proposition that an acoustic neuroma would predispose the cochlear system to an inflammatory process capable of harming hearing. Tr. at 147; Bigelow First Rep. at 8–9; Saunders at 8. And although Saunders’s authors acknowledged other diseases or precipitating events that might contribute to SNHL in patients with acoustic neuroma, Dr. Bigelow felt much of these proposed alternative causes were speculative and lacking in corroborating proof. Tr. at 147; Bigelow First Rep. at 8–9; Saunders at 8.

³¹ Dr. Bigelow acknowledged, however, that some individuals with an acoustic neuroma never develop hearing loss despite the risk. Tr. at 134.

No. 34-2) (“Moffat”) (identifying a 12 percent incidence of sudden SNHL in 284 patients with vestibular schwannomas; in 10 percent of patients, sudden SNHL was the presenting symptom); H. Berg et al., *Acoustic Neuroma Presenting as Sudden Hearing Loss with Recovery*, 94 Otolaryngology – Head & Neck Surgery 15, 17 (1986), filed as Ex. C, Tab 3 (ECF No. 34-4) (detecting a 13 percent incidence of sudden SNHL in 133 patients with acoustic neuromas); M. Pensak et al., *Sudden Hearing Loss and Cerebellopontine Angle Tumors*, Laryngoscope 1188, 1188 (1985), filed as Ex. C, Tab 4 (ECF No. 34-5) (“Pensak”) (pinpointing a 14.5 percent incidence of sudden SNHL in 69 patients with acoustic neuroma); E. Sauvaget et al., *Sudden Sensorineural Hearing Loss as a Revealing Symptom of Vestibular Schwannoma*, Acta Oto-Laryngological 592, 593 (2005), filed as Ex. C, Tab 5 (ECF No. 34-6) (“Sauvaget”) (finding a 20 percent incidence of sudden SNHL in 139 patients with vestibular schwannomas). The mechanism that causes a subclinical acoustic neuroma to become symptomatic with hearing loss is unknown. Tr. at 135. Dr. Bigelow noted that treatment for acoustic neuroma patients with hearing loss can include steroids, although they are not consistently effective. *Id.* at 124; Bigelow First Rep. at 11.

In addition, Dr. Bigelow stressed that acoustic neuromas can cause profound hearing loss regardless of the tumor size. Tr. at 124, 132. Dr. Bigelow noted that in his practice and in the literature, it was also fairly common for a patient to have a small tumor and yet experience profound hearing loss. *Id.* at 122–24; Bigelow First Rep. at 8–9; K-H. Jeong et al., *Abnormal Magnetic Resonance Imaging Findings in Patients with Sudden Sensorineural Hearing Loss*, 95 Medicine 1, 3 (2016), filed as Ex. A, Tab 2 (ECF No. 29-3) (“Jeong”) (recognizing that sudden SNHL is more frequently encountered in small tumors less than 1 centimeter than in medium-sized tumors greater than 1 centimeter); C. Lin et al., *The Clinical Characteristics and Treatment for Sudden Sensorineural Hearing Loss with Vestibular Schwannoma* Eur. Archives Otorhinolaryngology 839, 841–42 (2015), filed as Ex. A, Tab 3 (ECF No. 29-4) (“Lin”) (discussing how small tumors more easily cause sudden SNHL than larger tumors); Aslan at 581–82 (finding that sudden hearing loss is less frequently seen in larger tumors and there was no obvious frequency difference in cases with small tumors and medium tumors). Petitioner’s tumor was 5 millimeters (half a centimeter) in size. Tr. at 123; Ex. 5 at 58.

Dr. Bigelow then summarized M.R.’s medical history. Tr. at 114–21. He noted Petitioner’s first visit to a medical provider following his flu vaccination on October 27, 2016. *Id.* at 114; Ex. 7 at 113–15. The record from this ER visit reflected that Petitioner had experienced abrupt onset of painless vertigo beginning two days prior that turned into more constant symptoms on the day of presentation. Tr. at 114; Ex. 7 at 113–15. The examination was within normal limits except for some horizontal nystagmus. Tr. at 114; Ex. 7 at 113–15. The differential diagnoses include CPA tumor (also known as an acoustic neuroma), which Dr. Bigelow explained was a cerebellopontine angle. Tr. at 114–15; Bigelow First Rep. at 8; Ex. 7 at 113–15. This was the space between the cerebellum pons and the temporal bone—an area where the seventh and eighth nerves travel from the brainstem to get into the internal auditory canal. Tr. at 114. Petitioner also had a

CT scan during this visit, which came back negative, but Dr. Bigelow explained that it was often difficult to see an acoustic neuroma on a CT scan. Tr at 115; Ex. 7 at 113–15.

After this ER visit, Petitioner saw Dr. Goldrich on October 30, 2014, and the examination was unremarkable except findings suggesting hearing loss in the left ear. Tr. at 115–16; Ex. 5 at 43–46. An audiogram was also performed on that date confirming profound SNHL on the left side. Tr. at 116; Bigelow First Rep. at 7; Ex. 5 at 54–55. The audiologist’s impression was consistent with the examination, and there was an addendum added by Dr. Goldrich diagnosing Petitioner with left-sided SNHL. Tr. at 116–17; Ex. 5 at 55. On November 3, 2014, Petitioner saw Dr. Kwartler, who continued with treatment and scheduled an MRI, which Dr. Bigelow argued was intended to rule out acoustic neuroma or another type of tumor. Tr. at 118–19; Ex. 9 at 18. The noncontrast MRI scan³² revealed a round 5-millimeter structure in the left internal auditory canal, which most likely represented a vestibular schwannoma, and further MRI scans were recommended. Tr. at 120; Bigelow First Rep. at 7; Ex. 5 at 58. A later MRI from July 2021 noted the presence of a stable left-sided vestibular schwannoma. Tr. at 120–21; Ex. 31 at 12–13. The scan suggested that the tumor had not grown from the time of diagnosis. Tr. at 121; Ex. 31 at 12–13.

At the time of this hearing, Petitioner was considering a cochlear implant, which Dr. Bigelow agreed was reasonable if the hearing loss was centered in the cochlea. Tr. at 133–34, 148–49. However, he did not agree that this step was evidence that a vestibular schwannoma had not likely caused Petitioner’s sudden SNHL. *Id.* at 134. Cochlear implants used by patients with acoustic neuromas have variable results, and are in Dr. Bigelow’s experience often utilized even though the cochlea is not the most likely source of the SNHL. When an acoustic neuroma causes an issue with the cochlear labyrinthine artery that supplies blood to the cochlea, then the cochlear nerve may be functioning, and a cochlear implant will provide a benefit. *Id.* at 149–50. However, if the cochlear nerve is damaged such that it cannot transmit electrical signals from the cochlea, then the cochlear implant will not provide a benefit. *Id.*

Dr. Bigelow did not find Dr. Monsell’s theory of causation reliable, although he credited many of Dr. Monsell’s foundational points about the different possible means by which the ear’s functioning can be compromised.³³ Tr. at 127–29, 138; Bigelow First Rep. at 10. Masuda, which discussed the stress response theory embraced by Dr. Monsell, was now eight years old, with no

³² Dr. Bigelow explained that the noncontrast scan would not affect the results, but giving contrast (or gadolinium) provides more information, as acoustic neuromas will typically “light up” in the image produced, becoming bright and thus more easily identified. Tr. at 120.

³³ For example, Dr. Bigelow said it was conceivable that inflammation of the inner ear can compromise ion homeostasis. Tr. at 137. He agreed that NF- κ B is a transcription factor found throughout the body, with a significant amount present in the cochlea. *Id.* at 137–38. He agreed that NF- κ B was originally believed to have a protective effect of the inner ear. *Id.* at 138. He also agreed that when NF- κ B is pathologically activated, it can operate as a cellular stress pathway that can induce cytokine production. *Id.*

subsequent studies corroborating its findings. Tr. at 128–29; Masuda at 42. Otherwise, the concept Masuda embraced was not, in Dr. Bigelow’s understanding, widely accepted among the medical community. Tr. at 129. Dr. Bigelow also did not find the research from Merchant on the activation of NF- κ B cells applicable. Tr. at 128; Merchant at 158–59. Merchant’s authors induced an inflammatory response by injecting lipopolysaccharides into the abdomen of a mouse—hardly equivalent to vaccinating a human. Tr. at 128, 138–39, 141–43; Bigelow Second Rep. at 6; Merchant at 159. Otherwise, even if Dr. Monsell’s theory was correct, Dr. Bigelow would have expected steroid treatments to reduce inflammation, as reflected in the Adams & Seed study, and thus mitigate any sudden hearing loss. Tr. at 129; Adams & Seed at 537. Yet steroids were not effective for Petitioner—undermining the applicability of the stress response theory to this case. Tr. at 129.

Dr. Bigelow admitted that he had not submitted literature disputing the validity of the stress response theory, but he opined that if it were scientifically valid, there would be more cases of sudden hearing loss generally. Tr. at 144. He also denied literature support for the more general proposition that the flu vaccine causes or is associated with sudden hearing loss.³⁴ *Id.* at 126; Bigelow First Rep. at 9; Bigelow Second Rep. at 6. To the contrary—some large scale studies undermined the possibility of such an association. Baxter, for example, considered more than eight million vaccination doses, finding there was no correlation between vaccination and sudden hearing loss. Tr. at 126; Bigelow First Rep. at 9; Bigelow Second Rep. at 6–7; Baxter at 85. At most, Dr. Monsell could point to studies associating hearing loss with distinguishable vaccines, like the MMR (where the underlying wild infection (mumps) was *also* associated with hearing loss—unlike the wild flu virus). Tr. at 126–27; Bigelow First Rep. at 9–10; Asatryan at 1166, 1168. And Dr. Bigelow deemed VAERS data connecting the flu vaccine to SNHL to be particularly unreliable, since anyone can call and report a post-vaccination symptom, regardless of whether the claimed adverse effect actually happened. Tr. at 127.

Dr. Bigelow thus ultimately opined that the flu vaccine had not caused M.R.’s sudden SNHL. Tr. at 133. Though M.R. testified that after receiving the vaccine he experienced inflammation at the injection site and pain radiating up to his neck and left ear, Dr. Bigelow argued that this reaction did not likely have any bearing on his sudden hearing loss, since post-vaccination malaise-like reactions were common (and could cause some radiating pain as well). *Id.* at 125. And (contrary to Dr. Monsell’s opinion), Dr. Bigelow did not find that any of M.R.’s treating physicians proposed an association with the flu vaccine. *Id.* at 129. Thus, although Dr. Goldrich noted in a medical history section of a record that Petitioner’s hearing loss

³⁴ Dr. Bigelow referenced one case report from 2010, which discussed an instance of bilateral sudden deafness following the H1N1 vaccination, but the exact cause was not conclusively identified. Bigelow First Rep. at 9; H-H. Huang et al., *Bilateral Sudden Deafness Following H1N1 Vaccination*, 143 *Otolaryngology – Head & Neck Surgery* 849, 850 (2010), filed as Ex. A, Tab 9 (ECF No. 29-10). That version of the flu vaccine is not at issue in this case. Bigelow First Rep. at 9.

occurred after vaccination, he provided no professional commentary on whether there was any scientific/medical association between the vaccine and SNHL. *Id.* at 130; Ex. 7 at 25.

However, Dr. Bigelow did not deem the cause of M.R.’s hearing loss to be unknown. Rather, he opined that the most likely cause was his acoustic neuroma, giving its well-understood association with SNHL. Tr. at 130, 132; Bigelow First Rep. at 8, 10–11. Dr. Bigelow also opined that Petitioner’s vestibular schwannoma likely existed prior to his vaccination but was asymptomatic. Tr. at 135–36.

Dr. Bigelow concluded with a discussion of the timing of Petitioner’s onset, denying that the manifestation of M.R.’s vertigo and hearing loss four days after vaccination said anything about the likelihood of causation. Tr. at 125, 147–48; Bigelow First Rep. at 10. In support, he referenced Baxter, noting that it only showed a heightened risk of association in a longer timeframe than the four days at issue in this case. Tr. at 136; Bigelow First Rep. at 9; Baxter at 84.

III. Procedural History

M.R. filed his petition on August 18, 2016. ECF No. 1. By September 2016, Petitioner had filed all relevant medical records and a Statement of Completion. ECF No. 16. Respondent filed a Rule 4(c) report on November 8, 2016, contesting Petitioner’s right to compensation. ECF No. 18. The process of filing expert reports completed in the following year. After the matter was transferred to me on March 2, 2021, I held a status conference with the parties and subsequently scheduled the matter for a March 2021 one-day trial. ECF No. 50. The trial occurred as scheduled, and the matter is now ripe for resolution.

IV. Applicable Legal Standards

A. Petitioner’s Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). *See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006).*³⁵ In this case, Petitioner does not assert a Table claim.

³⁵ Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec’y of Health & Hum. Servs.*, 59 Fed. Cl. 121,

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.”

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.” *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden

124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (“[h]owever, in the past we have made clear that simply identifying a ‘plausible’ theory of causation is insufficient for a petitioner to meet her burden of proof” (citing *Moberly*, 592 F.3d at 1322)). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* “addresses the petitioner’s overall burden of proving causation-in-fact under the Vaccine Act” by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’” (quoting *Althen*, 418 F.3d at 1280)). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V,

2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Legal Standards Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as the “results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, “[m]edical records, in general, warrant consideration as trustworthy evidence.” *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner’s testimony and his contemporaneous medical records, the special master’s decision to rely on petitioner’s medical records was rational and consistent with applicable law”), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App’x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those

professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) (“[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms”).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, the Federal Circuit has also noted that there is no formal “presumption” that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at *19 (“[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything

reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). See *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the factors for analyzing the reliability of testimony are:

- (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. See, e.g., *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be “based on the

credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and the opinion proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App’x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 (“[a]ssessments as to the reliability of expert testimony often turn on credibility determinations”); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) (“this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act”).

D. Consideration of Medical Literature

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner’s case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) (“[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision”) (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App’x 875, 884 (Fed. Cir. 2013) (“[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered”).

ANALYSIS

I. Treatment of Hearing Loss Claims in the Vaccine Program

Program claimants have frequently argued that SNHL was attributable to a vaccine. Many (but not all) have not succeeded.³⁶ *See, e.g., Kelly v. Sec'y of Health & Hum. Servs.*, No. 16-878V, 2021 WL 5276373, at *23 (Fed. Cl. Spec. Mstr. Oct. 18, 2021), *mot. for review den'd*, 2022 WL 2314746 (Fed. Cl. Apr. 13, 2022) (dismissing the case and finding that petitioner failed to establish any preexisting condition that was aggravated by the flu vaccine); *Inamdar v. Sec'y of Health & Hum. Servs.*, No. 15-1173V, 2019 WL 1160341, at *16 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (referencing multiple prior negative decisions involving SNHL or hearing loss); *Donica v. Sec'y of Health and Hum. Servs.*, No. 08-625V, 2010 WL 3735707, at *1, 10 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (finding that the flu vaccine not demonstrated to cause adult hearing loss); *Hopkins v. Sec'y of Health & Hum. Servs.* Nos. 00-745V & 00-746V, 2007 WL 2454038, at *13 (Fed. Cl. Spec. Mstr. Aug. 10, 2007) (noting that the specific onset of hearing loss in child siblings after receipt of several vaccines could not be established). In most such cases, the *fact* of post-vaccination SNHL was not disputed, but the claimants could not demonstrate the vaccine was causal.

I recently decided entitlement in *Kelly*, a case in which it was similarly alleged that the flu vaccine had caused SNHL. *Kelly*, 2021 WL 5276373, at *1. Although that petitioner maintained a significant aggravation claim, I found that my determination would have been the same even if the petitioner had alleged a causation-in-fact claim, and a discussion of all three *Althen* prongs were incorporated in that decision. *Id.* at *24. Petitioner proposed two mechanisms, a rapid Type I sensitivity reaction and an autoimmune response. *Id.* at *25. There was limited evidence to support this connection, however, and petitioner's contention that SNHL could be driven by an autoimmune process was inconsistent with the timeframe presented. *Id.* I also found that petitioner's onset of less than two hours was too short to be deemed medically acceptable. *Id.* at *24.

In *Inamdar* (another case I decided), a petitioner argued that the flu vaccine had caused SNHL, with onset the following day, based on two theories. *Inamdar*, 2019 WL 1160341, at *5. First, the claimant argued that the vaccine "could cause the production of proinflammatory cytokines immediately upon vaccine administration." *Id.* But I determined that this argument relied too heavily on what was known about the wild virus rather than the vaccine. *Id.* at *6. The second

³⁶ As already noted, I am not bound by the decisions of my colleagues—or even the Court's decisions on review (except when stemming from a case I decided). *Boatmon*, 941 F.3d at 1358–59; *Hanlon*, 40 Fed. Cl. at 630. Nevertheless, special masters reasonably draw upon their overall, collective experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs.*, 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim"). They would thus be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

theory was that specific components of the vaccine “were structurally homologous with ganglioside receptors on the neuronal myelin contained in the inner ear tissue, and that antibodies generated in response to the vaccine could also cross-react with the self-myelin, resulting in tissue damage.” *Id.* I found, however, that this contention misapplied mechanisms relevant in other contexts. I also ruled that an alternative cause for the SNHL (the fact that the claimant was receiving antibiotics at the time) existed, as well as that the short onset was not preponderantly defended. *Inamdar*, 2019 WL1160341, at *19. A too-short onset has been a notable obstacle to recovery in other cases. *See, e.g., Donica*, 2010 WL 3735707, at *13 (two-hour post-vaccination onset of SNHL not demonstrated to be medically acceptable).

A different recent reasoned decision, by contrast, resulted in an entitlement decision favorable to the petitioner, and suggests the existence of some reliable science supporting the contention that a vaccine could cause abrupt hearing loss. *See Madigan v. Sec'y of Health & Hum. Servs.*, No. 14-1187V, 2021 WL 3046614, at *1, 4 (Fed. Cl. Spec. Mstr. June 25, 2021) (flu vaccine caused adult petitioner’s SNHL). In *Madigan*, the petitioner relied on the stress response theory (also utilized in this case) and a theory of reactivation of a latent HSV-1 infection. *Madigan*, 2021 WL 3046614, at *17. As observed in *Madigan*, that theory was not presented in prior adverse decisions like *Inamdar* or *Kelly*. In addition, Petitioner’s symptoms arose between *three to four days* post-vaccination—also consistent with the timeframe in this case. *Madigan*, 2021 WL 3046614, at *4, 20. *Madigan* offers positive parallels to this case—although (as discussed below) its petitioner did not possess so glaring an alternative explanation for his hearing loss.

II. An Alternative Cause/Factor Unrelated (Acoustic Neuroma) Most Likely Explains Petitioner’s SNHL

As noted above, even in cases where a petitioner meets his *prima facie* obligations under *Althen*, Respondent can still prevail if he then carries the burden (which shifts under such circumstances) of establishing preponderantly that a “factor unrelated” is the cause of the alleged injury. Section 13(a)(1)(B); *Schilling v. Sec'y of Health & Hum. Servs.*, No. 16-527V, 2022 WL 1101597, at *21 (Fed. Cl. Spec. Mstr. Mar. 17, 2022). The Vaccine Act provides that “factors unrelated to the administration of the vaccine,” are those “which are shown to have been the agent ... principally responsible for causing the petitioner’s illness, disability, injury, condition or death.” Section 13(a)(2)(B).

Here, the alternative cause evidence is strong enough to be dispositive of the claim overall—even without evaluating whether Petitioner met his initial burden³⁷—since it precludes

³⁷ Because the case turns on the second *Althen* prong, I need not fully consider whether the other two prongs were satisfied. I note, however, that Petitioner did offer a theory with many reliable components. The NF- κ B immune complex could theoretically be disrupted by cytokine-prompting events (including infection or vaccination), and it is possible an inflammatory environment in the ear could then trigger hearing loss. This theory was deemed sound and reliable in *Madigan*. *See Madigan*, 2021 WL 3046614, at *17. It was also demonstrated by Petitioner that *different* vaccines might be associated with SNHL, opening the door to the possibility that the same was true of the flu vaccine.

the determination that the vaccine “did cause” his SNHL (*Althen* prong two). *Snyder v. Sec'y of Health & Hum. Servs.*, 553 F. App'x 994, 1000 (Fed. Cir. 2014) (“‘no evidence should be embargoed from the special master’s consideration simply because it is also relevant to another inquiry under the statute’”) (*quoting Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012); *see also de Bazan*, 539 F.3d at 1353 (“[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case-in-chief”)).

As discussed above, the evidence in this case robustly supports the conclusion that Petitioner’s acoustic neuroma/vestibular schwannoma was the most likely cause of his SNHL.³⁸ Reliable evidence was offered to establish that acoustic neuromas frequently result in hearing loss. Moffat at 117; Pensak at 1188; Saunders at 26; Sauvaget at 593. Dr. Monsell for his part did not deny a potential causal relationship between sudden SNHL and the discovery of an existing vestibular schwannoma. *See* Tr. at 63, 91–92. Moreover, Dr. Bigelow persuasively established, over Dr. Monsell’s counterargument, that in this case the small size of the tumor was irrelevant—and in fact *more* likely to produce hearing loss than a larger one. Jeong at 3; Lin at 841–42; Aslan at 581–82. And Dr. Monsell’s efforts to diminish the likely role of the neuroma in causing Petitioner’s SNHL were otherwise unconvincing.

In addition, treaters largely embraced the neuroma as the causal explanation. Although there are instances where the vaccine’s causal role is discussed, it seems more commonly to reflect

Such evidence must, however, be weighed against the lack of evidence suggesting any association between the wild flu virus or vaccine and hearing loss, as well as larger-scale studies like Baxter (which may not disprove the possibility of an association, but certainly offer *some* reliable evidence casting doubt on the connection). There is also the fact, as pointed out by Dr. Bigelow, that the stress response theory embraced herein has not been corroborated in much (if any) subsequent literature or scientific studies. And the more general issue of how a vaccine, administered in the periphery of the human body, would lead to sufficient systemic inflammation to have a focal immunologic impact in the ear was largely not explained in Petitioner’s theory to any satisfying degree.

Petitioner’s third prong timeframe showing, by contrast, was a bit more persuasive. Petitioner’s four-day, post-vaccination onset was not disputed, and that timeframe is consistent with his theory about how long an aberrant cytokine-driven process would take to occur. Reliable science bulwarks it, and it is also consistent with the timeframe deemed medically acceptable in the few other favorable decisions involving hearing loss. *Madigan*, 2021 WL 3046614, at *20 (finding that a three-to-four-day onset was reasonable). Of course, Baxter suggests that if in fact there is any flu vaccine-SNHL risk at all, it does not come into play within a week’s time post-vaccination (since the odds ratio for that period was exceedingly low), but later. Baxter at 84–85. But the timeframe was reasonably substantiated otherwise.

³⁸ For these same reasons, I would not find in this case, under a “*Shyface*” analysis, that the flu vaccine and the neuroma were equally potentially causative, permitting an entitlement decision for Petitioner. *Shyface*, 165 F.3d at 1352–53. Not only did Dr. Bigelow *not* concede that the flu vaccine can be causal, but the evidence in this case preponderates far more strongly in favor of the neuroma as causal. And Dr. Monsell offered nothing that would illuminate how causation might come about in the context of both vaccination and the presence of an acoustic neuroma. *See, e.g.*, Tr. at 98.

an effort to record Petitioner's history than to evince reasoned opining as to cause. Ex. 9 at 14, 16, 18.³⁹ All of the above preponderantly supports the conclusion that it was the neuroma (which likely predicated vaccination) that produced Petitioner's SNHL and not the vaccine.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such as showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.⁴⁰

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

³⁹ It could be inferred from Petitioner's obtaining of a future flu vaccine exemption (as reflected in Ex. 27 at 214) that some treaters concurred as to the vaccine's likely causal role, and hence recommended Petitioner not receive the flu vaccine again. However, the record overall does not suggest or demonstrate that these same treaters *discounted* the neuroma's role—or even considered its causal role for that matter. And since special masters are never tied to a treater view, I do not give this particular item of evidence more weight than the ample record evidence of the acoustic neuroma itself.

⁴⁰ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.